Biotech Daily

Friday September 4, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PROTEOMICS UP 9%; PRESCIENT DOWN 8%**

*** DR BOREHAM'S CRUCIBLE: MAYNE PHARMA**

*** SAFETY BOARD BACKS MESOBLAST RESTEMCEL-L COVID-19 TRIAL**

*** PENNSYLVANIA $412k FOR REDHILL OPAGANIB FOR COVID-19**

*** S&P PROMOTES MACH7 INTO ALL TECHNOLOGY INDEX**

*** CSL $9.5m CEO PERFORMANCE RIGHTS AGM**

*** ALLAN GRAY REDUCES TO 13% OF STARPHARMA**

*** ONE FUNDS TAKES 10% OF BLUECHIIP**

MARKET REPORT

The Australian stock market fell 3.06 percent on Friday September 4, 2020, with the ASX200 down 187.1 points to 5,925.5 points. Eight of the Biotech Daily Top 40 stocks were up, 25 fell, six traded unchanged and one was untraded. All three Big Caps fell.

Proteomics was the best, up five cents or 9.1 percent to 60 cents, with 165,687 shares traded.

Antisense and Cynata climbed more than three percent; Compumedics, Next Science and Pharmaxis rose more than two percent; with Avita and Opthea up by less than one percent.

Prescient led the falls, down 0.5 cents or 7.6 percent to 6.1 cents, with 21.3 million shares traded.

Starpharma lost 7.1 percent; Pro Medicus fell 6.3 percent; Imugene, Kazia and Resmed were down more than five percent; CSL, Orthocell, Paradigm and Patrys fell four percent or more; Actinogen, Clinuvel, Cochlear, Dimerix, Medical Developments, Neuren, Oncosil, Osprey and Polynovo were down more than three percent; Alterity, Genetic Signatures, Immutep, Impedimed and Mesoblast shed two percent or more; with Nanosonics, Nova Eye, Telix and Volpara down by more than one percent.

DR BOREHAM'S CRUCIBLE: MAYNE PHARMA

By TIM BOREHAM

ASX code: MYX

Share price: 33.5 cents

Shares on issue: 1,679,068,131

Market cap: $562.50 million

Chief executive officer: Scott Richards

Board: Roger Corbett (chair), Mr Richards, Bruce Mathieson, Prof Bruce Robinson, Patrick Blake, Frank Condella, Nancy Dolan, Ian Scholes.

Financials (year to June 2020): revenue $457 million (down 13%), net loss $94.5 million (previously a $279 million deficit), earnings before interest tax depreciation and amortization $80.3 million (down 28%), cash $137.8 million (up 55%), debt $385.6 million (up 4%).

Identifiable major holders*: Investors Mutual 8.7%, Bruce Mathieson (and related entities) 6.2%
***** Lazard Asset Management held 5% but ceased to be a substantial shareholder on August 25

The trouble with being a generic drug maker is that, by their nature, the products are relatively easily replicated and not subject to trademark protection.

But the generics sector is capacious and with its entrée into the fast-growing US market Mayne grew to a multi-billion-dollar market cap entity, before "incessant and aggressive" price competition took its toll.

After all, what else is there to compete on other than price?

The first generics supplier might do OK after the branded drug's patent expires, but for the next entrants it's a case of a scrapping for a share of a smaller profit pie.

Having now reported three years of losses, Mayne wisely has refocused on the "specialty" sector, which refers to reworked drugs targeting specific or niche markets.

In the US, Mayne distributes 29 medicines on the essential medicines list and makes 15 of them in-house.

Notably, Mayne has a supersized 85 percent share of the US oral contraceptives market.

So, while Donald Trump strives to make America great again, it won't procreate again ... at least not in an unintended manner.

Playing the Mayne game in generics

In the company's apt words, Mayne Pharma's history is "intricate" and we're going to outline the abridged version.

Mayne Pharma previously was known as Halcygen Pharmaceuticals, which listed in June 2007 on the back of two licenced "super generics", suba-itraconazole (an antifungal) and minocycline (an antibiotic).

Then valued at a mere $17 million, Halcygen was the handiwork of its chief executive and chairman Dr Roger Aston. Halcygen was backed from the outset by pokies king Bruce Mathieson and his buddy Roger Corbett, the former Woolworths chief who remains Mayne's chairman.

Halcygen shared DNA with the Mayne Group, the logistics and health conglomerate cobbled together by inveterate acquirer Peter Smedley.

The late Mr Smedley's masterplan for an integrated hospital, drug making and drug distribution outfit foundered after some monumental missteps, including daring to tell surgeons how to carry out their business.

Global group Hospira ended up with the injectable products while Halcygen acquired the rights to the oral drugs.

Halcygen, which changed its name to Mayne Pharma in November 2010 essentially emerged from the detritus of the 175-year old Adelaide-based drug maker FH Faulding.

To this day, the business is based at Faulding's Salisbury facility although it also has a factory at Greenville in North Carolina.

The company bulked up with the $US652 million 2016 acquisition of Teva's generics portfolio in 2016, which delivered no fewer than 20 oral contraceptives.

This was funded by a monstrous $888 million rights issue and placement.

Along the way Mayne faced a US Department of Justice probe into alleged price fixing of two generic drugs (an antibiotic and a diabetes treatment).

Mayne bought the popular acne generic Doryx in 2015.

Pregnant with promise

Mayne's women's health portfolio includes 27 drugs either sold or in development.

But the company's biggest play is in the $US4 billion a year US contraceptives sector, spearheaded with novel combination E4/DSRP. Mayne licensed the rights to the drug – the be renamed the more consumer-friendly Nextstellis – from Mithra Pharma last November.

E4 refers to oestetrol, a natural oestrogen produced by the foetal liver during pregnancy. The DSRP bit refers to drospirenone (progestin). Believe it or not, E4/DRSP is the first oestrogen-based prophylactic in the US for 50 years - and the only one containing oestetrol.

Mayne claims that Nextstellis will offer a unique mechanism of action, with better efficacy, safety and bleeding control relative to other estrogen-based alternatives. As a native oestrogen, it's also kinder to Mother Nature.

In April, the company lodged an application with the US Food and Drug Administration and the paperwork was accepted in June.

"The FDA has a target action date of second quarter of calendar 2021 and we are planning to launch immediately on approval," Mr Richards told investors.

Also on the baby preventative front, in early July, Mayne entered a long term deal to supply the Nantong, China-based generics supplier Novast Laboratories with 13 generic contraceptive drugs. These include five new products not previously marketed by Mayne.

Meanwhile, the company is filing approval to market Nuvaring, the generic version of the biggest-selling contraceptive device in the US. The company licenced the Nuvaring vaginal ring containing oestrogen and progestogen from Mithra in February 2017.

By mid-2022, Mayne plans to have at least 35 women's health products on the market.

Also of interest …

While investors aren't quite convinced the company is back on track, there's no shortage of activity in Mayne's labs.

One example is an ongoing phase II study to support use of the anti-fungal Tolsura (a formulation of itraconazole) in coccidioidomycosis, a nasty respiratory disease caused by inhaling the seeds of certain types of fungi. Primary endpoint data is expected to be published in a learned journal in October.

Also, in the clinic is an itraconazole treatment for basal cell carcinoma nevus syndrome (BCCNS, also known as Gorlin Syndrome). A rare disorder but still viewed as a $US300 million market, BCCNS causes chronic lesions on the face and body.

Following a 2018 a phase IIb trial showing a "majority" of target lesions decreased in size, the company is eyeing a phase III trial this year.

Meanwhile, the company has started a phase II program for trifarotene, to treat lamellar ichthyosis. Lamellar what? It's a rare disease, causing severe skin scaling, for which there's no approved treatment.

A retinoic acid receptor-y agonist, trifarotene has orphan drug status in the US and Europe. Mayne has started to recruit the first of up to 120 patients, with top-line results by end of June 2021.

The curse of Covid

Nor surprisingly given the intensity of Covid-19 in the US, Mayne’s sales were affected, although the Greenville facility operated at record volumes.

Mr Richards describes the overall impact as “modest but mixed”, with little impact on generics and contract services.

“However, out-branded business was impacted by a decline in prescribing, driven by either reduced capacity or fewer patient visits.”

The company estimates that dermatology scripts fell 15 percent in March to May, but dispensing has since recovered to pre-virus levels. There’s also a silver lining in that three of the four dermatology brands increased market share in the six months to June 30, 2020.

Tolsura volumes had been growing nicely, but were affected because the drug is prescribed by infectious and respiratory surgeons who were somewhat pre-occupied.

“We had six months of growth in a slow market, but we are beginning to see growth again,” Mr Richards says. “It’s a pity that Covid-19 happened.”

Well, Scott, as they say: shit happens.

Finances and performance

Mayne’s reported deficit of $92.8 million for the 2019-’20 year was an improvement on the previous year’s $279 million shortfall - but a loss nonetheless.

The red ink reflects $99 million of impairment to the generics’ portfolio, taking cumulative write-downs since 2017 to $340 million.

Underlying earnings before interest tax depreciation and amortization (Ebitda) fell 28 percent to $80.3 million.

Covid-19 aside, management cited the usual reasons of intense generics competition, plus stock write-downs on discontinued products.

Other factors are the “managed care” aspect of health insurers becoming meaner and the effect of millions of Americans becoming jobless and no longer having insurance. “Everyone in the industry is grappling with managed care and we have a number of plans to mitigate that,” Mr Richards says.

A key trend is that retail generics accounted for only 25 percent of gross profit, down from 42 percent previously. The specialty and contract services accounted for 75 percent of profits, compared with 58 percent previously.

“We expect this ratio to continue to move favorably following launch of key women’s products pending with the FDA,” Mr Richards said.

Mayne shares peaked at $2.00 in August 2016. They tumbled to a nadir of 19.5 cents on March 19 this year, recovering to 47 cents on June 10. Still, that wasn't enough to prevent the stock from getting chucked out of the ASX200 index in mid-June.

And did we mention cost savings?

In 2019-'20 management found more than $30 million of cost reductions, half operating expenses and half research and development spend. Along the way, 10 percent of staff were given their marching orders.

The company's research and development fell by 35 percent to $32.7 million and is moving away from "volatile" retail generics to the favored women's health, dermatology and infectious diseases.

Dr Boreham's diagnosis:

It's clear that Mayne's biggest short-term growth gambit is Nextstellis, with targeted peak sales in the US of $US200 million a year. That assumes a mere two percent market share.

The company has also earmarked $US20 million in launch costs.

"Bringing this product to market will be transformational for Mayne," Mr Richards says.

Other key growth initiatives are building the Tolsura infectious diseases platform and expanding its dermatology and women's health lines.

Along the way, Mayne has been a nice gamble for pokies king Bruce Mathieson and his mate Roger Corbett.

But it looks like a hard grind for Mayne from here: the seven brokers covering the stock pencil in current financial year revenue of $498 million, with Ebitda of $118 million. These are the median averages.

The earnings estimates vary from $94 million to $135 million, depending on how the analysts treat the Nextstellis launch costs.

The brokers' 2021-'22 revenue projections average $609 million, with greatly improved earnings of $154 million (a range of $115 million to $198 million).

Their median 'price target' is a mere 38 cents a share, with only three brokers ascribing a 'buy' call (or similar).

Generically speaking, we concur that the stock does not exactly look like a bargain and it looks like a hard slog from here. But the worst, at least, might be over as the company moves to the value-added end of town.

Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort – generic or otherwise.

MESOBLAST

Mesoblast says its 300-patient phase III trial of remestemcel-L in patients with Covid-19-related acute respiratory distress syndrome has been recommended to continue.
Mesoblast said the independent data safety monitoring board reviewed the first 30 percent of the total target of randomized patients in the study, as well as the primary endpoint of all-cause mortality within 30 days of randomization and all safety data, and had "recommended continuation of the phase III trial".
In April, the company said it began enrolling the trial after 10 of 12 ventilator-dependent Covid-19 patients with acute respiratory distress syndrome (Ards) treated with its mesenchymal stem cell product had survived in a trial at New York's Mt Sinai Hospital, with nine no longer requiring ventilator support (BD: Apr 24, 30, May 6, 2020).
Today, Mesoblast said there would be further interim analyses when 45 percent and 60 percent of patients reached the primary endpoint.
Mesoblast said that patients were randomized 1 to receive either two intravenous infusions of remestemcel-L or placebo within five days, on top of maximal care.
Mesoblast chief medical officer Dr Fred Grossman said the company was pleased with the recommendation as the "trial seeks to confirm whether remestemcel-L improves survival in ventilated Covid-19 patients with moderate to severe Ards, where death rates remain high despite best existing treatments".
Earlier this week, Mesoblast said Monash Health had approved Melbourne and Sydney hospitals to join the US-based study (BD: Sep 2, 2020).
Today, the company said the trial was expected to complete recruitment this year.
Mesoblast fell 15 cents or 2.9 percent to $4.95 with 14.5 million shares traded.

REDHILL BIOPHARMA

Redhill says the State of Pennsylvania has awarded $US300,000 ($A412,329) to its opaganib for Covid-19 program.
Redhill said that the funds came from the Pennsylvania Covid-19 Vaccines, Treatments and Therapies Program and had been to its partner, the Hershey, Pennsylvania-based Apogee Biotechnology Corp, which licenced opaganib to Redhill.
(In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010)).
Today, the company said Apogee would conduct the research supported by the grant.
Earlier this year, the company said a 270-patient, phase II/III randomized, double-blind, parallel-arm, placebo-controlled study of opaganib, or Yeliva, for patients with severe acute respiratory syndrome coronavirus 2 (Sars-Cov-2), the cause of Covid-19, and had been approved in Italy, the UK, Russia and Mexico, and was under review in additional countries (BD: Apr 7, Jul 30, 2020).
Last week, Redhill said a parallel 40-patient phase II trial of opaganib in the US had passed the first US safety monitoring committee review and was advised to continue "with no changes" (BD: Aug 28, 2020).
Today, the company said the grant would fund pre-clinical mechanistic research to further expose opaganib's potential role in suppressing the extent or duration of Covid-19-related acute respiratory distress syndrome.
Redhill head of research and development Dr Reza Fathi said the grant would "help accelerate and expand the development of opaganib toward our goal of generating a robust data package to potentially support emergency use applications for Covid-19".
On the Nasdaq, Redhill was down six US cents or 0.76 percent to $US7.86 ($A10.81) with 155,170 shares traded.

STANDARD & POORS, MACH7 TECHNOLOGIES

Standard & Poor's Dow Jones Indices says it has promoted Mach7 to the S&P ASX All Technology Index, effective from September 21, 2020.

Standard & Poor's did not say any other biotechnology company had been promoted or demoted.

Mach7 fell 4.5 cents or 4.35 percent to 99 cents with 2.9 million shares traded.

CSL

CSL will vote to grant a long-term incentive of up to $9,524,069 in performance rights to chief executive officer Paul Perreault.

CSL said the proposed 32,732 performance shares were equivalent to 400 percent of Mr Perreault's base salary of $US1,751,000 ($A2,408,830) at September 1, 2020, and would be paid over four equal tranches.

Last year, the company proposed to grant Mr Perreault a long-term incentive of $US7,004,000 ($A10,425,722), equivalent to 400 percent of his base salary, which passed with 241,087,584 votes (91.65%) in favor and 21,967,834 votes (8.35%) against (BD: Sep 6, Oct 17, 2019).

In 2018, CSL said the proposal to issue Mr Perreault 'performance' rights worth up to $US6,128,500 ($A8,510,935) was supported by 219,444,916 votes (83.89%) and opposed by 42,134,292 votes (16.11%), which amounted to 9.3 percent of the company, sufficient to requisition extraordinary general meetings (BD: Oct 18, 2019).

Today, the company said it would vote on the remuneration report and the re-election of directors Bruce Brook, Carolyn Hewson and Pascal Soriot.

The meeting will be held online on October 14, 2020 at 10am (AEDT).

CSL fell $11.90 or 4.1 percent to $279.05 with 1.1 million shares traded.

STARPHARMA HOLDINGS

Allan Gray Australia says it has reduced its substantial holding in Starpharma from 53,431,698 shares (14.37%) to 48,891,666 (13.12%).

The Sydney-based Allan Gray said that between September 6, 2019 and September 1, 2020 it bought and sold shares, with the single largest sales between April 16 and September 1, 2020 of 1,206,239 shares for $1,716,853 or an average $1.42 a share.

Starpharma fell 12 cents or 7.1 percent to $1.58 with 2.3 million shares traded.

BLUECHIIP

One Funds Management says it has increased its substantial shareholding in Bluechiip from 50,000,000 shares (8.43%) 60,000,000 (10.12%).

The Sydney-based One Funds said it bought and sold shares between September 10, 2018 and September 2, 2020, and since its previous substantial shareholder notice in June 2020, the single largest purchase was 5,000,000 shares for $275,908 or 5.5 cents a share (BD: June 15, 2020).

Bluechiip fell 0.1 cents or 1.6 percent to 6.2 cents.